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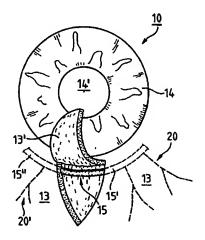
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(54) METHODE ET DISPOSITIF VISANT A AMELIORER LE DRAINAGE DE L'HUMEUR AQUEUSE DANS UN OEIL

(54) METHOD AND DEVICE TO IMPROVE AQUEOUS HUMOR DRAINAGE IN AN EYE



(57) Méthode visant à améliorer le drainage de l'humeur aqueuse dans un oeil par le canal de Schlemm. Selon cette méthode, l'humeur aqueuse sécrétée par le corps ciliaire est drainée dans les voies d'évacuation subséquentes vers un dispositif, afin de poursuivre le drainage. En injectant une substance, sous forme d'un liquide hydrophile ou d'une substance gazeuse biocompatible ou encore un mélange des deux, dans le canal de Schlemm exposé microchirurgicalement à un ou plusieurs endroits, le canal de Schlemm est élárgi localement par la pression hydraulique accrue. Au moyen de d'un élément support subséquemment dans la lumière du canal de Schlemm, les parois internes du canal sont supportées et tenues de façon permanente dans une position élargie. On peut ainsi assurer un drainage non-entravé de l'humeur aqueuse du canal de Schlemm par les voies d'évacuation subséquentes.

(57) The present invention relates to a method to improve aqueous humor drainage in an eye with a canal of Schlemm in which eye the aqueous humor secreted by the ciliary body is drained through the subsequent outflow pathways and to a device to maintain aqueous humor drainage. By means of a medium injected in the form of a hydrophilic liquid or a biocompatible gaseous medium or a mixture of the hydrophilic liquid and the gaseous medium into the canal of Schlemm microsurgically exposed at one or more locations, the canal of Schlemm is locally expanded by means of the increased hydraulic pressure. With a support element subsequently implanted in the lumen of the canal of Schlemm, the inner walls of this canal are supported and permanently held in an expanded position, whereby unimpeded drainage of the aqueous humor from the canal of Schlemm through the subsequent outflow pathways is ensured.

#### **ABSTRACT**

The present invention relates to a method to improve aqueous humor drainage in an eye with a canal of Schlemm in which eye the aqueous humor secreted by the ciliary body is drained through the subsequent outflow pathways and to a device to maintain aqueous humor drainage.

By means of a medium injected in the form of a hydrophilic liquid or a biocompatible gaseous medium or a mixture of the hydrophilic liquid and the gaseous medium into the canal of Schlemm microsurgically exposed at one or more locations, the canal of Schlemm is locally expanded by means of the increased hydraulic pressure. With a support element subsequently implanted in the lumen of the canal of Schlemm, the inner walls of this canal are supported and permanently held in an expanded position, whereby unimpeded drainage of the aqueous humor from the canal of Schlemm through the subsequent outflow pathways is ensured.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

- 1. A method to improve aqueous humor drainage in an eye, by which the aqueous humor secreted by the ciliary body is drained in the region of the iridocorneal angle through the trabecular meshwork in the canal of Schlemm and from there through the subsequent natural outflow pathways, characterized in that the canal of Schlemm, microsurgically exposed at one or more locations, is expanded in a first phase by a localized increased hydraulic pressure and then, in a second phase, for example, is supported by appropriate means implanted in the expanded lumen and is thus permanently held in an expanded position.
- 2. The method according to Claim 1, characterized in that the exposed canal of Schlemm is expanded with a hydrophilic liquid injected into the lumen thereof.
- 3. The method according to Claim 1, characterized in that the exposed canal of Schlemm is expanded with a gaseous, biocompatible medium injected into the lumen thereof.

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- 4. The method according to Claims 2 and 3, characteriz d in that the exposed canal of Schlemm is expanded with a mixture of the hydrophilic liquid and the gaseous medium injected into the lumen thereof.
- 5. The method according to Claim 1, characterized in that at least one axially oriented support element permanently supporting the inside wall of the canal of Schlemm is implanted in the expanded portion thereof.
- 6. The method according to Claims 1 and 5, characterized in that the support element inserted with its distal end into the expanded portion of the canal of Schlemm is held tightly against the inside wall of the incision by means disposed on the proximal end thereof.

- 7. The method according to Claims 1 and 5, characterized in that a support element which can be plastically deformed at least in its external diameter and which can return to its original shape because of thermal shape memory is implanted in the expanded portion of the canal of Schlemm.
- 8. The method according to Claim 7, characterized in that the support element is plastically deformed under normal human body temperature and after implantation is returned to its original shape as a result of body temperature and shape memory.

- 9. The method according to Claims 1 and 5, charact rized in that the canal of Schlemm is expanded in at least two portions positioned at intervals circumferentially spaced from each other, into which in each case the support element is implanted.
- 10. The method according to Claims 1,5 and 9, characterized in that the support element with outflow openings or the like distributed thereon and connected with the lumen thereof is implanted in the canal of Schlemm connected with the subsequent natural outflow pathways.
- 11. The method according to Claims 1 through 10, characterized in that on each of the two sides of the microsurgically exposed and expanded portion of the canal of Schlemm, one support element is implanted.
- 12. A device to perform the method according to Claim 1, in which the canal of Schlemm exposed in at least one place is expanded by means of a medium injected by an injection apparatus, characterized in that in the region of the locally expanded portion of the canal of Schlemm a support element supporting the inside wall and axially oriented thereto is introduced and placed such that the aqueous humor can permanently drain from the canal of Schlemm through the subsequent outflow pathways of the eye.

- 13. The device according to Claim 12, characterized in that the support element designed as a long tube is provided on the proximal end opposite the distal end with a contact collar designed flaring conically outward, preferably with a contact collar formed on it.
- 14. The device according to Claim 12, characterized in that analogously to the lumen (16) of the canal of Schlemm, the support element is designed axially somewhat arcuate or can be automatically deformed into an arcuate shape.

- 15. The device according to Claim 12, characterized in that the support element is designed conically tapering longitudinally from the proximal end to the other, distal end.
- 16. The device according to Claim 12, characterized in that the tubular support element is provided with multiple outflow openings circumferentially and longitudinally distributed at intervals and connecting with the inside.

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17. The device according to Claim 12, characterized in that the support element has two torus-shaped end portions axially spaced and provided with outflow openings, between which at least two, but preferably three webs are disposed circumferentially at intervals.

- 18. The device according to Claim 12, charact riz d in that the support element is designed from interlinked threads as a hollow cylindrical network provided with outflow openings.
- 19. The device according to Claim 18, characterized in that the network of the support element is plastically deformable and can be returned to its original shape by warming up.
- 20. The device according to Claims 18 and 19, characterized in that the threads of the network are manufactured from a nickel-titanium alloy with thermal shape memory.
  - 21. The device according to Claims 18 and 19, characterized in that the threads of the network are manufactured from a plastic with thermal shape memory.
  - 22. The device according to Claims 18 through 21, characterized in that the support element is designed from threads wound individually or counter to each other as a hollow cylindrical network.

23. The device according to one of Claims 18 through 21, characterized in

that the threads of the support element are bound to each other in a helicoidal network.

- 24. The device according to Claim 18, characterized in that the support element designed as a hollow cylindrical network is designed to expand automatically.
- 25. The device according to Claim 18, characterized in that the net-shaped support element is produced from a plurality of metal wires wound together.

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- 26. The device according to Claim 12, characterized in that the support element is manufactured in the form of a coil spring made from a single wire wound in a helix.
- 27. The device according to Claim 12, characterized in that the hollow cylindrical element is made of a biocompatible material, for example, of a suitable plastic, of stainless steel, of a noble metal, such as silver, gold, or platinum, or of a biological material.
- 28. The device according to Claim 12, characterized in that the hollow cylindrical support element is coated with suitable material to generate a desired biological reaction or to prevent an adverse biological reaction.

- 29. The device according to Claims 12, characterized in that the hollow cylindrical element is flexibly designed for automatic adaptation to the lumen of the canal of Schlemm in the direction of the theoretical longitudinal axis.
- 30. The device according to Claim 12, characterized in that the hollow cylindrical element is disposed by means of a separable connection on the injection apparatus.
- 31. The device according to Claim 12, characterized in that the injection apparatus is provided with a probe which is designed as a separable support element to be implanted in the lumen of the canal of Schlemm.
  - 32. The device according to Claims 12 and 31, characterized in that the hollow cylindrical support element is pushed onto the probe of the injection apparatus and can be emplaced by an axial movement of the probe relative to the support element or postionally stable into the expanded portion of the canal of Schlemm.

